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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,477	06/04/2002	Edmond D. Roussel	HER0050	1783

7590

04/14/2004

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,477	ROUSSEL ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 AND 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group I, claims 1 and 4 on 2/26/04 is acknowledged.

The traversal is on the ground(s) that because there is an alleged technical relationship between the groups which involves the same special technical feature, the restriction is improper.

To begin with, it is noted that all of the claims are written in terms of “use”, such that no process steps are provided. Contrary to applicant’s arguments, the various “uses” at least of claims 2 and 3 appear to pertain to processes of use of an independent process or product-by-process claim directed to a propionic acid bacterial strain. Since the material “used” in various applications in dependent claims is a strain having substantially the same properties as strains known in the art, unity of invention is lacking since the uses recited are also conventional. Applicants failed to address the evidence presented regarding the lack of a common inventive concept between the groups, in view of WO 97/19689, at pages 3-6 and FR 2741509, which demonstrate that propionic acid cultures, and various uses thereof cultures are known in the art. The requirement of unity of invention is not fulfilled because there is no technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features ” means **those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art**. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features, since a contribution over the prior art is lacking.

Applicant’s statement regarding inability to assess FR 2741509 for lack of translation is puzzling, since this reference was, in fact, cited by applicants and includes an English abstract. The other cited reference is WO 97/19689 as correctly interpreted. The error in designating as “WP” is regretted. It is noted that at least Mr. Roussel is an inventor of the WO patent and the French patent and of the instant application. The disclosures of the two documents appear closely related if not the same.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

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Upon reconsideration claims 1 and 4-9 will be examined on the merits to the extent that they pertain to a method of obtaining a propionic acid bacterial food preparation in various forms. Claims 2 and 3 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-9 provide for the use of propionic bacteria, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 4-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1 and 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of "not very autolytic". This is a term of degree. The term "not very" in claim 1 is a relative term which renders the claim indefinite. The term "not very" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation at least 2 g/l, and the claim also recites "and preferably more than 4 g/l of propionic acid and/or of propionates" which is the narrower statement of the range/limitation. Claim 5 also includes a "preferably" clause, while claim 6 includes a "notably". These claims are indefinite for the reasons outlined for claim 1.

Claim 1 is vague and indefinite in the recitation "as the case may be". It cannot be readily determined what circumstances are intended by this.

In claim 1 it is unclear what is intended by "a current food composition or a dietetic or medicinal composition". It is unclear how different compositions are to be obtained by a single culture incubated in a certain manner. How is the nature of the composition assessed? Also how is it "prepared so that the bacteria are protected at least partially against gastric acidity"?

Claim 1 is vague and indefinite in the recitation of "YEL" medium. This is not art recognized term.

Claim 9 is confusing in the recitation of "bifid bacteria". The correct term is *Bifidobacterium*.

For the sake of clarity it is recommended that "characterizes in that" be replaced by "wherein".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roussel *et al.* (WO 97/19689) taken with Roussel *et al.* (WO 98/27991).

The invention is directed to the use of propionic acid bacteria which are not very autolytic which have been selected for their ability to produce at least 2 g/l of propionic acid and/or of propionates alone or in combination with lactic acid or *Bifidobacterium* to obtain a food composition having certain properties.

Roussel *et al.* '689 disclose propionic acid bacteria which are used to produce food compositions. The propionic acid bacteria have been selected as being not very autolytic and to produce propionic acid at least to some extent, as shown on page 11, paragraph 3. See, also page 9 wherein strain LS 410 is disclosed, which is not very autolytic and which is resistant to bile salts.

The reference is silent regarding cultivation of propionic acid bacteria at 30° C in YEL medium containing lactate. However, Roussel '991 disclose cultivation at 30° C in YEL medium in several rounds of cultivation. See, e.g., page 9, lines 30 et seq.. Inasmuch as the propionic acid bacteria may be provided with lactic acid bacteria, it can be reasonably presumed that at least some lactate is present during the culturing process. In addition, these strains of interest are known to produce propionic and acetic acid (Roussel '689, page 2, lines 33-35). This reference also discloses individual fractions of dry or hydrated preparations presented in the form of fractions containing at least 10⁸ cells (page 5). These compositions are gastroresistant. The results discussed at page 7 of Roussel '689 strongly suggest that the propionic acid bacteria have properties of adhesion on colonocytes since the microorganisms reside in the colon. The propionic acid bacteria compositions contain lactic acid and/or *Bifidobacterium*.

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The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Roussel *et al.* '689 by using the specific culture media as suggested by Roussel *et al.* '991 in order to obtain a food composition containing propionic acid bacteria having a high production ability of propionic acid for the expected benefit of promoting the growth of lactic acid bacteria or *Bifidobacterium* in the colon and achieving the concomitant protective effects of probiotic cultures.

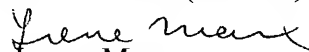
Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx
Primary Examiner
Art Unit 1651